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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/551,101 | 09/26/2005 | Richard Mueller | ZP192-05009 | 1624 |
| 22884 | 7590 | 10/23/2007 | EXAMINER | |
| MIDDLETON & REUTLINGER 2500 BROWN & WILLIAMSON TOWER LOUISVILLE, KY 40202 | | | SIGLER, JAY R | |
| | | ART UNIT | PAPER NUMBER | |
| | | 4111 | | |
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| | | 10/23/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|---------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/551,101 | MUELLER, RICHARD |
| | Examiner Jay R. Sigler | Art Unit 4111 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 October 2007.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-54 is/are pending in the application.
 4a) Of the above claim(s) 16-54 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-15 is/are rejected.
 7) Claim(s) 1 is/are objected to.
 8) Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 26 September 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>08 June 2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species II in the reply filed on 9 October 2007 is acknowledged.
2. Claims 16-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9 October 2007.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: in the second to last paragraph in the specification, the reference number **201, 202, and 713** are not shown in the drawings. Applicant's cooperation is requested in checking the specification for other reference characters that are not shown in the drawings.
4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "**330**" has been used to designate both lower caps of the locking assemblies in the different embodiments of the invention. It appears that several drawings of the multiple embodiments use the same reference character for similar elements. Applicant's cooperation is requested in checking the drawings and specification for other reference characters that refer to different elements.

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5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The disclosure is objected to because of the following informalities: in paragraph [0013] there is a word missing it the end of the last sentence.

Appropriate correction is required.

Claim Objections

7. Claim 1 is objected to because of the following informalities: it is unclear as to whether or not the applicant is claiming the rod as part of the invention. In the portion starting "a housing coupled", the language "for receiving a rod" is used and then later the language "wherein said rod" is used. "For receiving a rod" does not appear to claim the rod as part of the invention, but "wherein said rod" does appear to claim the rod as part of the invention. Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Vienney et al. (WO 03/024343). U.S. Patent Application Publication 2005/0240180 is the national stage entry of WO 03/024343 and is relied upon as a translation. The following references are made to US 2005/0240180. Vienney et al. teaches a **bone fixation apparatus for a rod system comprising: a bone anchor** (1 not including 10 and 11; Paragraph [0035]) **having a proximal end capable of engaging a driving device and a distal end for engaging a bone; a housing** (10 and 11) **coupled to said proximal end of said bone anchor having opposed spaced-apart flanges** (10 and 11) **extending longitudinally defining a channel therebetween for receiving a rod** (seen in Figure 1), **said flanges having an outer surface and an inner surface having female threads therein** (Paragraph [0037], Line 1-3); **a locking assembly** (3 and 4) **for locking said surgical rod to said housing in contact with said proximal end of said bone anchor** (Paragraph [0041]); **wherein said locking assembly further comprises an upper cap** (4) **and a lower cap** (3) **joined by a post** (33) **and rotatable relative one to the other** (Paragraph [0040], Last Sentence), **wherein said upper cap is a generally cylindrical member having an outer surface containing threads** (41) **thereon and an inner cavity** (34, 44, and 47) **and an upper surface**

and a lower surface and wherein said inner cavity further comprises an opening to receive said post (34); and wherein said lower cap comprises an upper surface and a lower semi-cylindrical surface (32) for engaging said rod. The rod is insertable in the channel and the locking assembly is used to lock the rod into the housing (seen in Figure 1; Paragraph [0041]).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-4, 6-8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuan et al. (WO 01/52758) in view of Cotrel (U.S. Patent 5,154,719).

Yuan et al. teaches a **bone fixation apparatus for a rod system comprising: a bone anchor** (see Abstract; taken to be embodied by fastener portion) **having a proximal end capable of engaging a driving device and a distal end for engaging a bone;** a **housing** (see Abstract; taken to be embodied by head portion) **coupled to said proximal end of said bone anchor having opposed spaced-apart flanges (230 and 232) extending longitudinally defining a channel therebetween for receiving a rod (228); a locking assembly** (see Abstract; taken to be embodied by locking cap); **wherein said locking assembly further comprises an upper cap (220a) and**

a lower cap (220b) joined by a post (298) and rotatable relative one to the other (Page 19; First Paragraph), wherein said upper cap is a generally cylindrical member having an inner cavity (282) and an upper surface and a lower surface and wherein said inner cavity further comprises an opening to receive said post (288); and wherein said lower cap comprises an upper surface and a lower semi-cylindrical surface (299) for engaging said rod.

The rod is insertable in the channel and the locking assembly is used to lock the rod into the housing (see Abstract). Yuan et al. does not teach the threaded engagement between the locking assembly and the housing, but does teach a means (284, 286, 294, and 296) for a locking engagement between the locking assembly and the housing.

Cotrel teaches a bone fixation apparatus including a locking system (10, 11, and 12) that uses a threaded engagement (7 and 9) in order to lock the rod in translation and in rotation (see Abstract). It would have been obvious to substitute the locking engagement of Yuan et al, in view of Cotrel, with a threaded engagement because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. The predictable results being creating a locking engagement between the locking assembly and housing.

Concerning claims 2, 3, 6, 7 and 10, Yuan et al. includes different embodiments of the bone anchor including a fixed screw (Figure 1; 26), fixed hook (Figure 1; 46), or polyaxial screw (Figure 13, 226).

Concerning claims 4, 8, and 11, Yuan et al. teaches an extension 302 of the lower cylindrical surface.

12. Claims 5, 9, 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuan et al. (WO 01/52758) in view of Cotrel (U.S. Patent 5,154,719) as applied to claims 4, 8, or 11 above, and further in view of Richelsoph et al. (U.S. Patent Application 2003/0187442). Yuan et al., in view of Cotrel, fairly suggests the invention as shown above, but does not fairly suggest timing the threads. Richelsoph et al. teaches carefully controlling and timing threads in order to guarantee an element stops exactly where it must (Paragraph [0015]). It would have been obvious to someone of ordinary skill in the art at the time of the invention to time the threads in the invention of Yuan et al., in view of Cotrel, in order to guarantee an element stops exactly where it must. Concerning claims 13 and 14, Yuan et al. teaches a the screw having a depression (Figure 12a; seen at the top of the screw 214) and the housing has an appurtenance (234; embodied by something subordinate to another, more important thing; appurtenance. (n.d.). *Dictionary.com Unabridged* (v 1.1). Retrieved October 17, 2007, from Dictionary.com website:

<http://dictionary.reference.com/browse/appurtenance>

13. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yuan et al. (WO 01/52758) in view of Cotrel (U.S. Patent 5,154,719) and Richelsoph et al. (U.S. Patent Application 2003/0187442) as applied to claim 14 above, and further in view of Bono et al. (U.S. Patent 6, 755, 829). Yuan et al., in view of Cotrel, fairly suggests the invention as shown above and a means (232 and 234) for keeping the polyaxial screw

in the housing, but does not fairly suggest using a depression and appurtenance to keep the screw in the housing. Bono et al. teaches using a depression (between 146) and appurtenance (158) to keep two elements (140 and 153) together (see Abstract; Lines 10-13; taken to be embodied by a bayonet mount). It would have been obvious to substitute the means of Yuan et al, in view of Cotrel and Richelsoph, with the means of Bono et al. because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. The predictable results being keeping elements together, namely the housing and bone screw.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

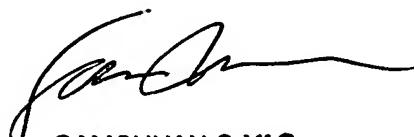
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jay R. Sigler whose telephone number is (571) 270-3647. The examiner can normally be reached on Monday through Thursday from 8 AM to 4 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on (571) 272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


18 October 2007
JRS


SAMCHUAN C. YAO
SUPERVISORY PATENT EXAMINER